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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/284,147	03/17/1999	MICHEL LANQUETIN	GEI-067	1949

7590 09/29/2003

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EXAMINER
QAZI, SABIHA NAIM

ART UNIT	PAPER NUMBER
1616	3

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/284,147	LANQUETIN ET AL.	
	Examiner	Art Unit	
	Sabiha Qazi	1616	

-- The MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25,27-30,33,34 and 36-40* is/are pending in the application.

4a) Of the above claim(s) *36-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25, 27-30, 33, 34 and 36-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Acknowledgment is made of the response and amendments filed in paper no. 29 and declaration in paper no. 30 (dated 7/7/2003). Claims 25, 27-30, 33, 34, and 36-40 are pending. Claims 25, 27-30, 33, 34 and 36-40 are rejected.

The applicants have received several Office Actions on the subject matter of the said claims. The Examiner does not understand why the Applicants are adding new claims that have the **same** subject matter as the claims that were rejected several times. Rather than amending the claims to overcome the rejections, the applicants prolong the prosecution time of the application by adding similar claims that have already been rejected.

Same rejections mailed in our previous actions apply on new claims 36-40 because the new claims are similar to the original claims when these rejections were made.

New claims must be canceled.

The Examiner notes that claim 34 is amended to overcome the rejection made in the last Office Action. However, the dependent claims were not amended.

The Examiner has considered the declaration filed in paper no. 30. Examiner would like to know about the amounts used in each case. Amounts should be the same for any side-by-side comparison. Examiner will re-consider the declaration after knowing the amounts of estradiol and nomegestrol used for comparative examples. See MPEP 716.02(e). As presented it gives the ranges.

However, at the time of claimed invention, nomegestrol acetate was known for the pharmacological profiles which applicants referred in Table 3 on page 6 of the declaration. This information in Table 3 is not applicants invention?

All rejections are maintained.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 25, 27-30, 33, 34 and 36-40 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administering the combination of nomegesterol and estradiol in a continuous or intermittent fashion, from 21-25 days

per month" (see lines 4-6, on page 4 of the specification), does not reasonably provide enablement for "continuously without interruption". The ranges of estradiol and Nomegestrol acetate overlap the presently claimed ranges.

The question is the unlimited time in claim. How long will be "continuous". Specification discloses i.e. 21-25 days so claims must be limited to no. of days supported by the disclosure.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Since all the showing and discussions were based on continuous administration without bleeding, the invention as claimed does not find support by the disclosure of the invention.

Claims 25, 27-30, 33, 34 and 36-40 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for estradiol, does not reasonably provide enablement for every estrogen estrogens, estradiol esters etc. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The invention provides a method of treating estrogeneic deficiencies in women comprising administering without interruption combination of a 0.5 to 3 mg of an estrogenic compound and 1.5 to 3.75 mg of nomegestrol acetate.

Claims are not limited to the scope to the extent of support in disclosure so that one skilled in the art without undue experimentation can practice invention.

A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See In re Riat et al. (CCPA 1964) 327 F2d 685, 140 USPQ 471; In re Barr et al. (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

Claims 24, 25, 27-30, 33 and 34 and 36-40 stand rejected under 35 U.S.C. 103(a) as obvious over Plunkett et al. (US Re. 36,247) and Fraser et al. (Medline, AN 89261206, abstract of

Maturitas, (1989 Mar) 11(1), 21-34). Both the references teach the art, which embraces instantly, claimed invention.

1. Determining the scope and contents of the prior art.

Plunkett teaches a method of hormonal treatment for menopausal disorders involving continuous administration of progestogens and estrogens. See the entire document especially lines 40-51, col. 2; lines 63-67, col. 2; lines 1-67, col. 3; lines 18-25, and lines 1-5, col. 4; lines 46-50, col 6.

The reference teaches continuous and uninterrupted administration of progestogen and estrogen. The actual unit dosage are selected according to conventionally known methods, e.g. body weight of patient and biological activity of hormones with the ultimate goal of producing the desired result with minimum quantities of hormones. It does not specifically discloses progestogen, nomegesterol acetate.

Fraser teaches the effects of the addition of nomegestrol acetate. All patients experienced a regular, progestogen-induced withdrawal bleed each month; and histological, ultra structural and biochemical changes were induced within the endometrium by all

doses (0.5 mg, 1.0 mg; and 2.5 mg) is a potent progestogen. See the abstract.

2. Ascertaining the differences between the prior art and the claims at issue.

Instant claims are drawn to a method of treating deficiencies of estrogen by continuously administering a combination of estrogen and nomagesterol acetate. Plunkett et al differs from the instant invention in that it does not specifically name nomegesterol acetate however, Fraser teaches the advantages of using nomegesterol acetate.

3. Resolving the level of ordinary skill in the pertinent art.

Therefore, it would be obvious to one skilled in the art at the time of invention to prepare

a composition to administer continuously combination of estrogen and nomegesterol as

progestagen due to the advantages taught by the prior art. See as cited above.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Motivation is to use estrogen and progestogen continuously as taught by Plunkett et al. and use nomegesterol as progestagen because it gives in all patients regular, progestogen-induced withdrawal bleed each month; and histological, ultrastructural and biochemical changes were induced within the endometrium by all doses (0.5 mg, 1.0 mg; and 2.5 mg) is a potent progestogen. Thus, there has been ample motivation provided by the teachings of both the references cited above to prepare the instant invention in absence of any criticality or unexpected results.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing

date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is 703-305-3910. The examiner can normally be reached on every business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

SABIHA QAZI, PH.D
PRIMARY EXAMINER